

### **I. AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions and listings of claims in the application.

#### **Listing of Claims:**

1. (original) A pharmaceutical composition comprising a pharmacologically active ingredient and an amount of benzethonium chloride and an amount of phenoxyethanol wherein the amounts of benzethonium chloride and phenoxyethanol are effective to inhibit microbial growth, and wherein the composition is not formulated for topical administration.

2. (original) The composition of claim 1, further defined as comprising benzethonium chloride in a concentration of from about 0.001 to about 1.0%, and phenoxyethanol in a concentration of from about 0.01 to about 2.0%.

3. (original) The composition of claims 1, 2, 45, 46 or 47, wherein said pharmacologically active ingredient is a cardiovascular agent.

4. (original) The composition of claim 3, wherein said cardiovascular agent is diltiazem, digoxin, dopamine, digitalis, procainamide hydrochloride, lidocaine, verapamil, or levostatin.

5. (original) The composition of claims 1, 2, 45, 46 or 47, wherein said pharmacologically active ingredient is an agent for the treatment of the gastrointestinal system or liver.

6. (original) The composition of claim 5, wherein said agent for the treatment of the gastrointestinal system or the liver is an antacid, a digestant or an emetic.

7. (original) The composition of claim 5, wherein said agent for the treatment of the gastrointestinal system or the liver is lipase, furosamide, morphine, scopolamine, ranitidine.

8. (canceled)

9. (canceled)

10. (original) The composition of claims 1, 2, 45, 46 or 47, wherein said pharmacologically active agent is a hematologic agent.

11. (original) The composition of claim 10, wherein said hematologic agent is heparin, streptokinase, urokinase, tissue plasminogen activator, or aspirin.

12. (original) The composition of claims 1, 2, 45, 46 or 47, wherein said pharmacologically active agent is an antihistamine.

13. (original) The composition of claim 12, wherein said antihistamine is theophylline, diphenhydramine, hydroxyzine or fexofenadine.

14. (original) The composition of claim 12, wherein said antihistamine is fexofenadine.

15. (original) The composition of claim 14, comprising about 0.005% benzethonium chloride, and about 0.25% phenoxyethanol.

16. (original) The composition of claims 1, 2, 45, 46 or 47, wherein said pharmacologically active ingredient is an antimicrobial.

17. (original) The composition of claim 16, wherein said antimicrobial is penicillin, amoxycillin, kanamycin, neomycin, erythromycin, tetracycline, doxycycline, norfloxacin, or cyclosporin.

18. (original) The composition of claims 1, 2, 45, 46 or 47, wherein said pharmacologically active agent is an antiepileptic or anti-seizure agent.

19. (original) The composition of claim 18, wherein said antiepileptic or anti-seizure agent is phenytoin, dilantin, or phenobarbital.

20. (original) The composition of claims 1, 2, 45, 46 or 47, wherein said pharmacologically active agent is a sedative or hypnotic.

21. (original) The composition of claim 20, wherein said sedative or hypnotic is scopolomine, fexofenadine, or methaqualone.

22. (original) The composition of claims 1, 2, 45, 46 or 47, wherein said pharmacologically active agent is a diuretic.

23. (original) The composition of claim 22, wherein said diuretic is furosemide, amiloride, aminophylline, or theobromide.

24. (original) The composition of claims 1, 2, 45, 46 or 47, wherein said pharmacologically active ingredient is a psychopharmacologic agent.

25. (original) The composition of claim 24, wherein said psychopharmacologic agent is an anti-psychotic or an antidepressant.

26. (original) The composition of claims 1, 2, 45, 46 or 47, wherein said pharmacologically active ingredient is an anti-migraine agent.

27. (original) The composition of claims 1, 2, 45, 46 or 47, wherein said pharmacologically active agent is a hormone.

28. (original) The composition of claims 1, 2, 45, 46 or 47, wherein said pharmacologically active agent is a protein or peptide.

29. (original) The composition of claims 1, 2, 45, 46 or 47, further comprising a second active agent.

30. (previously presented) The composition of claim 29, wherein said second active agent is a cardiovascular agent, an agent for the treatment of gastrointestinal disorders, a hematologic agent, an antihistamine, an antimicrobial, an antiepileptic, an anti-seizure agent, a sedative, a hypnotic, a diuretic, a psychopharmacologic agent, an anti-migraine agent, a hormone, a protein or a peptide.

31. (currently amended) The composition of claims 1, 2, 45, 46 or 47, wherein said composition is a liquid, suspension, emulsion, solution, mixture, ~~cream~~, inhalant, aerosol, ~~gel~~, ~~ointment~~, suppository, powder, tablet.

32. (currently amended) The composition of claims 1, 2, 45, 46 or 47, wherein said composition is administrable parenterally, ~~via mucosa~~, ~~by~~ suppository, by inhalation, or orally, ~~aurally, or ocularly~~.

33. (previously presented) A pharmaceutical carrier composition for use as a carrier of a pharmaceutically active ingredient, wherein said carrier comprises an amount of benzethonium chloride and an amount of phenoxyethanol wherein the amounts of benzethonium chloride and phenoxyethanol are effective to inhibit microbial growth in said composition, and wherein the carrier composition is not formulated for topical administration.

34. (original) The pharmaceutical carrier composition of claim 33, further defined as comprising benzethonium chloride in a concentration of from about 0.001 to about 1.0%, and phenoxyethanol in a concentration of from about 0.01 to about 2.0%.

35. (previously presented) The pharmaceutical carrier composition of claims 33 or 34, wherein said pharmaceutically active ingredient is a cardiovascular agent, an agent for the treatment of gastrointestinal disorders, a hematologic agent, an antihistamine, an antimicrobial, an antiepileptic, an anti-seizure agent, a sedative, a hypnotic, a diuretic, a psychopharmacologic agent, an anti-migraine agent, a hormone, a protein or a peptide.

36. (previously presented) The pharmaceutical carrier composition of claims 48, 49 or 50, wherein said pharmaceutically active ingredient is a cardiovascular agent, an agent for the treatment of gastrointestinal disorders, a hematologic agent, an antihistamine, an antimicrobial, an antiepileptic, an anti-seizure agent, a sedative, a hypnotic, a diuretic, a psychopharmacologic agent, an anti-migraine agent, a hormone, a protein or a peptide.

37. (currently amended) A vial for containing multiple dosages of a pharmacologically active ingredient, wherein said vial contains a solution comprising said active ingredient and an amount of benzethonium chloride and an amount of phenoxyethanol wherein

the amounts of benzethonium chloride and phenoxyethanol are effective to inhibit microbial growth in said composition, said solution formulated for administration by a route selected from the following: parenteral, ~~mucosal~~, ~~ocular~~, ~~aural~~, oral, suppository, inhalation.

38. (original) The vial of claim 37, further defined as comprising benzethonium chloride in a concentration of from about 0.001 to about 1.0%, and phenoxyethanol in a concentration of from about 0.01 to about 2.0%.

39. (original) The vial of claims 37 or 38, wherein said pharmacologically active ingredient is a cardiovascular agent, an agent for the treatment of gastrointestinal disorders, a hematologic agent, an antihistamine, an antimicrobial, an antiepileptic, an anti-seizure agent, a sedative, a hypnotic, a diuretic, a psychopharmacologic agent, an anti-migraine agent, a hormone, a protein or a peptide.

40. (currently amended) A pharmaceutical package for containing multiple dosages of a pharmacologically active ingredient, wherein said package contains a solution comprising said active ingredient and an amount of benzethonium chloride and an amount of phenoxyethanol wherein the amounts of benzethonium chloride and phenoxyethanol are effective to inhibit microbial growth in said composition, the benzethonium chloride being present in a concentration of about 0.001% to about 0.07%, and the phenoxyethanol being present in a concentration of about 0.01% to about 0.45%, said solution formulated for administration by a route selected from the following: parenteral, ~~mucosal~~, ~~ocular~~, ~~aural~~, oral, suppository, inhalation.

41. (previously presented) The pharmaceutical package of claim 40, wherein said pharmacologically active ingredient is a cardiovascular agent, an agent for the treatment of gastrointestinal disorders, a hematologic agent, an antihistamine, an antimicrobial, an antiepileptic, an anti-seizure agent, a sedative, a hypnotic, a diuretic, a psychopharmacologic agent, an anti-migraine agent, a hormone, a protein or a peptide.

42. (original) A method of inhibiting microbial growth in a non-topically-administrable solution comprising a pharmacologically active ingredient, said method comprising adding benzethonium chloride and phenoxyethanol to said solution.

43. (original) The method of claim 42, wherein benzethonium chloride is added in a concentration of from about 0.001 to about 1.0%, and phenoxyethanol is added in a concentration of from about 0.01 to about 2.0%.

44. (original) The method of claims 42 or 43, wherein said pharmacologically active ingredient is a cardiovascular agent, an agent for the treatment of gastrointestinal disorders, a hematologic agent, an antihistamine, an antimicrobial, an antiepileptic, an anti-seizure agent, a sedative, a hypnotic, a diuretic, a psychopharmacologic agent, an anti-migraine agent, a hormone, a protein or a peptide.

45. (previously presented) A pharmaceutical composition comprising a pharmacologically active ingredient, an amount of benzethonium chloride and an amount of phenoxyethanol, wherein the amounts of benzethonium chloride and phenoxyethanol are effective to inhibit microbial growth, and wherein the benzethonium chloride is present in a concentration of from about 0.001 to about 0.005%, and the phenoxyethanol is present in a

concentration of from about 0.01 to about 0.25% and wherein the composition is not formulated for topical administration.

46. (currently amended) A pharmaceutical composition comprising a pharmacologically active ingredient and an amount of benzethonium chloride and an amount of phenoxyethanol wherein the amounts of benzethonium chloride and phenoxyethanol are effective to inhibit microbial growth, and wherein the composition is formulated for administration by a route selected from the following: parenteral, ~~mucosal, ocular, aural~~, oral, suppository, inhalation.

47. (original) The pharmaceutical composition of claim 46, further defined as comprising benzethonium chloride in a concentration of from about 0.001 to about 1.0%, and phenoxyethanol in a concentration of from about 0.01 to about 2.0%.

48. (previously presented) A pharmaceutical carrier composition for use as a carrier of a pharmaceutically active ingredient, wherein said carrier comprises an amount of benzethonium chloride and an amount of phenoxyethanol wherein the amounts of benzethonium chloride and phenoxyethanol are effective to inhibit microbial growth in said composition, and wherein the benzethonium chloride is present in a concentration of from about 0.001 to about 0.005%, and the phenoxyethanol is present in a concentration of from about 0.01 to about 0.25% and wherein the carrier composition is not formulated for topical administration.

49. (currently amended) A pharmaceutical carrier composition for use as a carrier of a pharmaceutically active ingredient, wherein said carrier comprises an amount of benzethonium chloride and an amount of phenoxyethanol wherein the amounts of benzethonium chloride and



phenoxyethanol are effective to inhibit microbial growth in said composition, and wherein the carrier is formulated for administration by a route selected from the following: parenteral, ~~mucosal, ocular, aural,~~ oral, suppository, inhalation.

50. (original) The pharmaceutical carrier composition of claim 49, further defined as comprising benzethonium chloride in a concentration of from about 0.001 to about 1.0%, and phenoxyethanol in a concentration of from about 0.01 to about 2.0%.

51. (previously presented) A method of inhibiting microbial growth in a solution comprising a pharmacologically active ingredient, said method comprising adding benzethonium chloride and phenoxyethanol to said solution, wherein the benzethonium chloride is added to be in a concentration of from about 0.001 to about 0.005%, and the phenoxyethanol is added to be in a concentration of from about 0.01 to about 0.25% and wherein the solution is not formulated for topical administration.

52. (previously presented) The method of claim 46, wherein said pharmacologically active ingredient is a cardiovascular agent, an agent for the treatment of gastrointestinal disorders, a hematologic agent, an antihistamine, an antimicrobial, an antiepileptic, an anti-seizure agent, a sedative, a hypnotic, a diuretic, a psychopharmacologic agent, an anti-migraine agent, a hormone, a protein or a peptide.

53. (previously presented) The pharmaceutical carrier composition of claims 48, 49 or 50, wherein said pharmaceutically active ingredient is a cardiovascular agent, an agent for the treatment of gastrointestinal disorders, a hematologic agent, an antihistamine, an antimicrobial,

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an antiepileptic, an anti-seizure agent, a sedative, a hypnotic, a diuretic, a psychopharmacologic agent, an anti-migraine agent, a hormone, a protein or a peptide.